UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

SECURITIES AND EXCHANGE COMMISSION,	1:04CV1613
Plaintiff,	**C.A. No.___-_____**
v.	JUDGE POLSTER
DERRICK S. MCKINLEY,	
Defendant.	MAG. JUDGE BAUGHMAN

COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission") alleges the following:

1. Derrick McKinley, a former vice president and medical director of Gliatech, Inc., ("Gliatech") a pharmaceutical company, sold Gliatech stock while in possession of material, non-public information concerning problems with Gliatech's primary product Adcon-L Adhesion Barrier Gel ("Adcon-L"). During a twelve-month period from August 1999 to August 2000, McKinley sold short 221,000 shares of Gliatech stock in a series of transactions, reaping profits of approximately $1.6 million. McKinley was employed at Gliatech as Vice President of Medical Affairs and Medical

Director through September 21, 1999. McKinley obtained the material, non-public information about Adcon-L in connection with his employment at Gliatech. By selling shares while in possession of this material, non-public information in 1999 and 2000, McKinley breached his duty of trust and confidence to the shareholders of Gliatech. Alternatively, with respect to his trades in 2000, after he left Gliatech, McKinley misappropriated material, non-public information concerning Adcon-L in breach of his duty of trust and confidence to Gliatech.

2. From the outset of his trading, McKinley was aware of three major problems involving Gliatech's primary product, Adcon-L, a gel used to reduce scarring in patients following back surgery. By August 1999, McKinley was aware that: (1) a study of U.S. clinical trials of Adcon-L ("U.S. Adcon-L Study") submitted by Gliatech to the U.S. Food and Drug Administration ("FDA") had defects that called its reliability into question; (2) there were defective packaging and sterility problems associated with Adcon-L; and (3) there were complaints of cerebral spinal fluid leaks ("CSF leaks") in patients following surgery where Adcon-L was used. In October 1999, the FDA issued an import ban that kept shipments of Adcon-L from entering the U.S. The ban resulted from unresolved FDA concerns including the defective packaging and sterility problems of Adcon-L. In March 2000, news of complaints of CSF leaks became public. In August 2000, news of an FDA investigation challenging the integrity and results of the Adcon-L Study became public. Each time the bad news about Adcon-L became public, the price of Gliatech stock dropped. McKinley profited from each decline in Gliatech's stock price.

3. McKinley, directly and indirectly, has engaged and, unless enjoined, will continue to engage in transactions, acts, practices, and courses of business which constitute and will constitute violations of Sections 17(a)(1), 17(a)(2) and 17(a)(3) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §77q(a)(1), §77q(a)(2), and §77q(a)(3)], Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §78j(b)], and Rule 10b-5 [17 C.F.R. §240.10b-5] promulgated thereunder.

4. The Commission brings this action pursuant to Section 20(b) of the Securities Act [15 U.S.C. §77t(b)] and Sections 21(d) and 21A of the Exchange Act [15 U.S.C. §§78u(d) and 78u-1] for an order permanently restraining and enjoining McKinley, ordering disgorgement of unlawful profits and imposing civil penalties.

JURISDICTION AND VENUE

5. The Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Sections 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(e) and 78aa].

6. McKinley, directly and indirectly, has made use of the means and instruments of transportation and communication in interstate commerce, of the means and instrumentalities of interstate commerce, of the mails, and of the facilities of a national quotation system in connection with the transactions, acts, practices, and courses of business alleged herein within the jurisdiction of the Northern District of Ohio and elsewhere.

THE DEFENDANT

7. McKinley, age 44, resides in Highland Heights, Ohio. McKinley was employed at Gliatech from June 1997 until he resigned on September 21,1999. From

January 1998 until he left Gliatech, McKinley was Vice President of Medical Affairs and its Medical Director.

ENTITY INVOLVED

8. At all relevant times, Gliatech was a Delaware corporation. Gliatech's main offices were located in Beachwood, Ohio. Gliatech was primarily a research and development company of products used to improve surgical outcomes and to treat neurological disorders. At all relevant times, Gliatech's common stock was traded on the National Association of Securities Dealers' Automated Quotation System.

9. From at least September 1999 until 2000, Gliatech had an Insider Trading Policy that prohibited all of its directors, officers and employees who possessed material, non-public information relating to Gliatech from trading on that information. The policy also specifically prohibited short sales while in possession of material, inside information. No later than September 1999, prior to his leaving Gliatech, McKinley received a copy of the policy. By signing the policy, McKinley attested that he had read, understood, and agreed to adhere to Gliatech's Insider Trading Policy.

ADCON-L

10. Adcon-L Adhesion Barrier Gel ("Adcon-L") is a gel-like substance, which is applied to the patient's incision site during back surgery. The purpose of Adcon-L is to reduce scarring following back surgery. In December 1996, Gliatech submitted its application to distribute Adcon-L in the United States to the FDA. After the FDA's approval in May 1998, Adcon-L became Gliatech's only product to be marketed in the United States and its major source of revenue.

MCKINLEY'S KNOWLEDGE OF PROBLEMS WITH ADCON-L

Integrity Problems with U.S. Adcon-L Study

11. In December 1997, Gliatech's management, scientists and physicians, including McKinley, met with the FDA and the FDA's advisory panel to review Gliatech's application for commercial distribution of Adcon-L ("Panel Meeting"). At the conclusion of the meeting, the Advisory Panel recommended to the FDA that the FDA approve Gliatech's application, but with certain conditions.

12. One of the conditions was for Gliatech to conduct an Intraobserver Reliability Study ("Reread Study") to evaluate the reliability of the technique used by the radiologist to measure the presence of scar tissue in patients who had been treated with Adcon-L.

13. The other condition of the Advisory Panel's recommendation required Gliatech to submit the final results of the U.S. Adcon-L Study. Completion of the study was also an express condition set by the FDA when it approved Gliatech's application for Adcon-L in May 1998.

14. In November 1997, just weeks prior to the Panel Meeting, Gliatech's independent statisticians analyzed data from the U.S. Adcon-L Study ("November Analysis"). McKinley was aware that the November Analysis did not show any benefit to patients from using Adcon-L.

15. In January 1998, McKinley and the project manager for the U.S. Adcon-L Study participated in the Reread Study. McKinley did not conduct the Reread Study in accordance with good clinical practices (GCP). Specifically, as the radiologist read the magnetic resonance imaging films ("MRIs"), McKinley recorded the scores in pencil on

the case report forms. At times the radiologist changed his mind and McKinley was required to correct some of the scores he had just entered on the case report forms. When this occurred, McKinley erased the first score and entered the new score. GCP guidelines required McKinley to record the data in pen, and make changes by crossing out the old number, entering the new number and signing and dating the change. Because of these irregularities, the results from the Reread Study lacked integrity for purposes of supporting any submission to the FDA.

16. McKinley substituted scores from the Reread Study for the original scores in the U.S. Adcon-L Study. Specifically, in October 1998, at McKinley's direction, the project manager of the U.S. Adcon-L Study forwarded data from the Reread Study to Gliatech's independent statisticians with instructions to substitute the original scores with scores from the Reread Study and to reanalyze the data.

17. After the Reread scores were substituted for the original scores, the U.S. Adcon-L Study showed that Adcon-L was effective.

18. In March 1999, Gliatech submitted the final report of the U.S. Adcon-L Study with the substituted data to the FDA without telling the FDA that the data had been substituted.

19. Gliatech's failure to tell the FDA about the data substitution caused integrity problems with the U.S. Adcon-L Study, which made it unreliable.

Adcon-L's Sterility Problem

20. In the spring of 1999, FDA inspectors detected sterility problems with Adcon-L's packaging at Gliatech's contract manufacturer of Adcon-L, located in the

Netherlands. In March and April 1999, the FDA cited the contract manufacturer and Gliatech, respectively, for issues related to the defective packaging and sterility problems.

21. Pursuant to FDA guidelines, Gliatech conducted a health hazard evaluation. In May 1999, Gliatech issued a health hazard evaluation, which concluded that the packaging defects posed a minimal health risk to patients.

22. Before issuing the report, Gliatech's then vice president of Regulatory Affairs, Ray Silkaitis, gave a version of the hazard evaluation to McKinley for him to review and sign. However, McKinley refused to sign the report and instead provided detailed comments highlighting numerous false statements throughout the seven-page report. McKinley believed that Gliatech management had not adequately addressed the sterility problems with the Adcon-L packaging. On the last page, McKinley summarized his conclusion in the following note to Silkaitis.

> Ray,
>
> At this point in time, this health hazard evaluation is very inaccurate and misleading. Anytime a potentially contaminated product (the Adcon-L tube) is introduced into a sterile field, the possibility of contamination and infection exists. If this infection spreads into the central nervous system, then it can be life threatening. The only responsible thing to do is a recall. I will not sign this document in its current form, unless the recommended changes are made.
>
> Derrick
> 5/24/99

Adcon-L's Complaints of CSF Leaks

23. During the spring and summer of 1999, McKinley became aware of complaints of cerebral spinal fluid leaks in patients who had been treated with Adcon-L. As Gliatech's medical director, McKinley reviewed these complaints. McKinley knew that Gliatech's shareholders did not know about the complaints of CSF leaks.

24. On July 23, 1999, McKinley sent a memorandum and a list of complaints to Gliatech's management regarding that included CSF leaks. In his memorandum McKinley urged Gliatech management to notify the medical community about the increased risk for CSF leaks and to report them to the FDA.

25. In early September 1999, a surgeon who had participated in the Adcon-L Study, learned of complications from Adcon-L. One of these resulted in the death of a patient. On September 14, 1999, the surgeon wrote a letter to Gliatech management in which he urged them to notify physicians and the FDA of these complications. McKinley was copied on the letter.

26. McKinley knew that Gliatech had not notified physicians and the FDA about the complaints of CSF leaks in patients treated with Adcon-L.

MCKINLEY'S FRAUDULENT SECURITIES TRANSACTIONS

McKinley's short sales in August and September 1999

27. In August and September1999, McKinley was aware of material, non-public information that: (1) results of the U.S. Adcon-L Study submitted by Gliatech to the FDA had several defects that called its reliability into question; (2) there were defective packaging and sterility problems; and (3) there were complaints of cerebral spinal fluid leaks (CSF leaks) in patients following surgery where Adcon-L was used.

28. While in possession of this material, non-public information about Adcon-L, McKinley engaged in a series of short sales. From August 17, 1999 to September 10, 1999, McKinley sold 66,000 shares of Gliatech stock that he did not actually own. In the securities industry, this is known as "short selling." A short seller expects to profit when the stock price declines.

29. On September 7, 1999, the FDA issued a Warning Letter to Adcon-L's manufacturer based upon the manufacturing deficiencies, including the packaging defects and sterility problems it had detected the previous spring. In fact, among other things, the Warning Letter alluded to Gliatech's characterization of the Adcon-L packaging (as "double sterile barrier") as "inadequate." In its letter, the FDA also warned that Adcon-L may be detained upon entry into the United States until the violations, including the packaging and sterility problems, were corrected.

30. On October 8, 1999, Gliatech issued a press release disclosing the Warning Letter and the import alert acknowledging that Adcon-L may be detained. After the public announcement that the FDA had issued the import alert, Gliatech's stock dropped 24%.

31. McKinley profited from the decline in Gliatech's stock price. His total profits were approximately $605, 213.

McKinley's short sales in January and February 2000

32. After he left Gliatech in September 1999, McKinley became a confidential informant to the FDA. In November and December 1999, McKinley provided the FDA with information about the complaints of CSF leaks.

33. After learning about the complaints from McKinley, the FDA initiated an investigation into the complaints. On January 5 and February 5, 2000, McKinley visited the FDA offices to discuss the complaints.

34. Following his January 5 interview with the FDA, McKinley began to short Gliatech stock. Between January 6 and February 15, 2000, he sold short a total of 92,000 shares of Gliatech stock.

35. During the time of his trades in January and February 2000, McKinley was aware of material, non-public information that: (1) results of the U.S. Adcon-L Study submitted by Gliatech to the FDA had several defects that called its reliability into question; and (2) there were complaints of CSF leaks in patients following surgery where Adcon-L was used.

36. On March 13, 2000, Gliatech finally filed the medical reports for the complaints including the CSF leaks and, thereby, disclosed them to the public. The day after Gliatech disclosed the CSF complaints, its stock price declined by 8%.

37. McKinley profited from the decline in Gliatech's stock price. His total profits were approximately $53,178.

McKinley's short sales in the summer of 2000

38. On February 5, 2000, McKinley met with the FDA and provided a copy of the November Analysis that showed Adcon-L was not effective. McKinley suggested that the FDA investigate events relating to the U.S. Adcon-L Study, which then triggered a two-month investigation into data integrity issues. During this investigation, the FDA interviewed McKinley about the U.S. Adcon-L Study several times during July and August 2000.

39. In May 2000, Gliatech and Guilford Pharmaceuticals, Inc ("Guilford") announced a plan to merge their businesses. Within weeks of the announcement of the anticipated $233 million merger, McKinley contacted Guilford. McKinley called Guilford's General Counsel and its CEO, respectively. In his call to the CEO, McKinley said that he wanted to make sure that the CEO understood that McKinley had material information about Adcon-L that he wanted to discuss. Because McKinley's attorney

refused to meet with Guilford, McKinley and Guilford never discussed the substance of McKinley's information.

40. In July and August 2000, McKinley sold short an additional 63,000 Gliatech shares. At the time of these short sales, McKinley was aware of Gliatech's integrity problems with the Adcon-L. He also knew that the public did not know about Adcon-L's integrity problems.

41. On August 23, 2000, the FDA held a "closeout meeting" with Gliatech and Guilford in which they discussed the results of their data integrity investigation. During that meeting, the FDA investigator stated that they believed that data had been falsified and that the substitution of the original data was fraudulent. Citing the FDA's findings, on August 28, 2000, Gliatech and Guilford announced that they were terminating the proposed merger. Trading in Gliatech was halted on August 28, 2000. The following day, Gliatech opened at $9.47, down 60%.

42. McKinley profited from the decline in Gliatech's stock price. His total profits were approximately $932,999.

COUNT I
Violations of Section 17(a)(1) of the Securities Act
[15 U.S.C. §77q(a)(1)]

43. All preceding paragraphs are realleged and incorporated by reference herein.

44. By engaging in short sales of Gliatech stock while in possession of material, non-public information concerning problems with Adcon-L, McKinley breached his duty of trust and confidence to the Gliatech shareholders.

45. Alternatively, with respect to his short sales in 2000, after he left Gliatech, McKinley misappropriated the material, non-public information concerning problems with Adcon-L in breach of his duty of trust and confidence to Gliatech.

46. By the conduct alleged above, McKinley in the offer or sale of Gliatech securities by the use of means or instruments of transportation or communication in interstate commerce or by the use of the mails, directly or indirectly, employed devices, schemes or artifices to defraud.

47. McKinley acted with scienter when he engaged in the conduct alleged in this Count.

48. By reasons of the activities alleged in this Count, McKinley violated Section 17(a)(1) of the Securities Act [15 U.S.C. §77q(a)(1)].

COUNT II

Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §77q(a)(2) and §77q(a)(3)]

49. Paragraphs 1 through 42 are realleged and incorporated by reference herein.

50. By engaging in short sales of Gliatech stock while in possession of material, non-public information concerning problems with Adcon-L, McKinley breached his duty of trust and confidence to the Gliatech shareholders.

51. Alternatively, with respect to his short sales in 2000, after he left Gliatech, McKinley misappropriated the material, non-public information concerning problems with Adcon-L in breach of his duty of trust and confidence to Gliatech.

52. By the conduct alleged above, McKinley, in the offer or sale of Gliatech securities by the use of means or instruments of transportation or communication in

interstate commerce or by the use of the mails, directly or indirectly, obtained money or property by means of untrue statements of material facts and omissions to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading and engaged in transactions, practices or courses of business which would and did operate as a fraud or deceit upon purchasers and prospective purchasers of such securities.

53. By reasons of the activities alleged in this Count, McKinley violated Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§77q(a)(2) and 77 q(a)(3)].

COUNT III

Violations of Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 [17 C.F.R. §240.10b-5] promulgated thereunder

54. Paragraphs 1 through 42 are realleged and incorporated by reference herein.

55. By engaging in short sales of Gliatech stock while in possession of material, non-public information concerning problems with Adcon-L, McKinley breached his duty of trust and confidence to the Gliatech shareholders.

56. Alternatively, with respect to his short sales in 2000, after he left Gliatech, McKinley misappropriated the material, non-public information concerning problems with Adcon-L in breach of his duty of trust and confidence to Gliatech.

57. By the conduct alleged above, McKinley, in connection with the purchase and sale of Gliatech securities by the use of the means and instrumentalities of interstate commerce, by the use of the mails, and by the use of the facilities of a national securities exchange, directly and indirectly: employed devices, schemes, and artifices to defraud;

Relief, in a form consistent with Rule 65(d) of the Federal Rules of Civil Procedure, enjoining defendant Derrick S. McKinley, individually, his agents, servants, employees,

made untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and engaged in acts, practices and courses of business which would and did operate as a fraud and deceit upon the purchasers and sellers of such securities.

58. McKinley acted with scienter when he engaged in the conduct alleged in this Count.

59. By reason of the activities alleged in this Count, McKinley violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 [17 C.F.R. §240.10b-5] promulgated thereunder.

PRAYER FOR RELIEF

THEREFORE, the Commission respectfully requests that this Court:

I.

Find that McKinley committed the violations charged and alleged above.

II.

Grant a Final Order of Permanent Injunction, Civil Penalties, and Other Equitable Relief, in a form consistent with Rule 65(d) of the Federal Rules of Civil Procedure, enjoining defendant Derrick S. McKinley, individually, his agents, servants, employees, assigns, attorneys, and those persons in active concert or participation with him who receive actual notice of the Final Judgment by personal service or otherwise, and each of them, from, directly or indirectly, engaging in acts, practices, and courses of business in violation of Sections17(a)(1), 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §77q(a)(1), §77q(a)(2), and §77q(a)(3)].

III.

Grant a Final Order of Permanent injunction, Civil Penalties, and Other Equitable Relief, in a form consistent with Rule 65(d) of the Federal Rules of Civil Procedure, enjoining defendant Derrick S. McKinley, individually, his agents, servants, employees, assigns, attorneys, and those persons in active concert or participation with him who receive actual notice of the Final Judgment by personal service or otherwise, and each of them, from, directly or indirectly, engaging in acts, practices, and courses of business in violation of Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 [17 C.F.R. §240.10b-5] promulgated thereunder.

IV.

Grant an Order requiring McKinley to pay to the registry of this Court disgorgement of his ill-gotten gains plus prejudgment interest.

V.

Grant an Order requiring McKinley to pay civil penalty penalties pursuant to Section 21A of the Exchange Act [15 U.S.C. §78u-1].

VI.

Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

VII.

Grant an Order for such further relief as the Court may deem appropriate and proper.

Dated: August 12, 2004

Respectfully submitted,

Joy Marchbanks Boddie
Texas Bar No. 2542200
boddiej@sec.gov (e-mail)

Jarett B. Decker
District of Columbia Bar No. 436436
deckerj@sec.gov (e-mail)

Attorneys for Plaintiff
United States Securities and Exchange Commission
175 West Jackson Boulevard, Suite 900
Chicago, Illinois 60604
Telephone: (312) 353-7390
Facsimile: (312) 353-7398